

§ 1312.44 Request for hearing or appearance; waiver.

(a) Any applicant entitled to a hearing pursuant to § 1312.42 and who desires a hearing on the denial of his application for an import, export, or transshipment permit shall, within 30 days after the date of receipt of the denial of his application, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) Any applicant entitled to a hearing pursuant to § 1312.42 may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(c) If any applicant entitled to a hearing pursuant to § 1312.42 fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing unless he shows good cause for such failure.

(d) If the applicant waives or is deemed to have waived this opportunity for the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1312.47 without a hearing.

[37 FR 15923, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1312.45 Burden of proof.

At any hearing on the denial of an application for an import, export, or transshipment permit, the Administrator shall have the burden of proving that the requirements for such permit pursuant to sections 1002, 1003, and 1004 of the Act (21 U.S.C. 952, 953, and 954) are not satisfied.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1312.46 Time and place of hearing.

(a) If any applicant for an import, export, or transshipment permit requests a hearing on the issuance or denial of

his application, the Administrator shall hold such hearing. Notice of the hearing shall be given to the applicant of the time and place at least 30 days prior to the hearing, unless the applicant waives such notice and requests the hearing be held at an earlier time, in which case the Administrator shall fix a date for such hearing as early as reasonably possible.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

§ 1312.47 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order on the issuance or denial of the application for and import, export, or transshipment permit. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon the applicant.

[37 FR 15924, Aug. 8, 1972. Redesignated at 38 FR 26609, Sept. 24, 1973]

PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II CHEMICALS

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AUTHORITY: 21 U.S.C. 802, 830, 871(b), 971.

SOURCE: 54 FR 31665, Aug. 1, 1989, unless otherwise noted.

§ 1313.01 Scope.

Procedures governing the importation, exportation, transshipment and in-transit shipment of listed chemicals pursuant to section 1018 of the Act (21 U.S.C. 971) are governed generally by that section and specifically by the sections of this part.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995]

§ 1313.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13969, Mar. 24, 1997]

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§ 1313.05 Requirements for an established business relationship.

To document that an importer or exporter has an established business relationship with a customer, the importer or exporter must provide the Administrator with the following information in accordance with the waiver of 15-day advance notice requirements of § 1313.15 or § 1313.24:

(a) The name and street address of the chemical importer or exporter and of each regular customer;

(b) The telephone number, contact person, and where available, the facsimile number for the chemical importer or exporter and for each regular customer;

(c) The nature of the regular customer's business (*i.e.*, importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(d) The duration of the business relationship;

(e) The frequency and number of transactions occurring during the preceding 12-month period;

(f) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical importer or exporter and regular customer;

(g) The method of delivery (direct shipment or through a broker or forwarding agent); and

(h) Other information that the chemical importer or exporter considers relevant for determining whether a customer is a regular customer.

[72 FR 17407, Apr. 9, 2007]

§ 1313.08 Requirements for establishing a record as an importer.

To establish a record as an importer, the regulated person must provide the Administrator with the following information in accordance with the waiver of the 15-day advance notice requirements of § 1313.15:

(a) The name, DEA registration number (where applicable), street address, telephone number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(b) The frequency and number of transactions occurring during the preceding 12 month period.

[72 FR 17407, Apr. 9, 2007]

IMPORTATION OF LISTED CHEMICALS

§ 1313.12 Requirement of authorization to import.

(a) Each regulated person who imports a listed chemical that meets or exceeds the threshold quantities identified in § 1310.04(f) or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, shall notify the Administrator of the importation not later than 15 days before the transaction is to take place.

(b) A completed DEA Form 486 must be received by the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the importation. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media not later than 15 days prior to the importation.

(c) The 15-day advance notification requirement for listed chemical imports may be waived for the following:

(1) Any importation that meets both of the following requirements:

(i) The regulated person has satisfied the requirements for reporting to the Administration as a regular importer of the listed chemicals.

(ii) The importer intends to transfer the listed chemicals to a person who is a regular customer for the chemical, as defined in § 1300.02 of this chapter.

(2) A specific listed chemical, as set forth in paragraph (f) of this section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

(d) For imports where advance notification is waived pursuant to paragraph (c)(1) of this section, the DEA Form 486 must be received by the Drug Enforcement Administration, Import/Export Unit, on or before the date of importation through use of the mailing address listed in § 1313.12(b) or through use of electronic facsimile media.

(e) For importations where advance notification is waived pursuant to paragraph (c)(2) of this section no DEA Form 486 is required; however, the regulated person shall submit quarterly reports to the Import/Export Unit, Drug Enforcement Administration, no later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The report shall contain the following information regarding each individual importation:

- (1) The name of the listed chemical;
- (2) The quantity and date imported;
- (3) The name and full business address of the supplier;
- (4) The foreign port of embarkation; and
- (5) The port of entry.

(f) The 15 day advance notification requirement set forth in paragraph (a) has been waived for imports of the following listed chemicals:

- (1) Acetone.
- (2) 2-Butanone (or Methyl Ethyl Ketone or MEK).
- (3) Toluene.

[54 FR 31665, Aug. 1, 1989, as amended at 59 FR 51367, Oct. 11, 1994; 60 FR 32464, June 22, 1995; 66 FR 46520, Sept. 6, 2001; 67 FR 49569, July 31, 2002; 72 FR 17407, Apr. 9, 2007; 75 FR 10683, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1313.13 Contents of import declaration.

(a) Any List I or List II chemical listed in § 1310.02 of this chapter may be imported if that chemical is necessary for medical, commercial, scientific, or other legitimate uses within the United States. Chemical importations into the United States for immediate transfer/transshipment outside the United States must comply with the procedures set forth in § 1313.31.

(b) Any regulated person who desires to import a threshold or greater quantity of a listed chemical shall notify the Administration through procedures set forth in § 1313.12 and distribute three copies of DEA Form 486 as directed in § 1313.14.

(c) The DEA Form 486 must be executed in triplicate and must include the following information:

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(1) The name, address, telephone number, and, where available, the facsimile number of the chemical importer; the name, address, telephone number, and, where available, the facsimile number of the broker or forwarding agent (if any); and

(2) The name and description of each listed chemical as it appears on the label or container, the name of each chemical as it is designated in 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof; and the gross weight of the shipment given in kilograms or parts thereof; and

(3) The proposed import date, the foreign port of exportation and the first U.S. Customs Port of Entry; and

(4) The name, address, telephone number, telex number, and, where available, the facsimile number of the consigner in the foreign country of exportation; and

(5) The name, address, telephone number, and where available, the facsimile number of the person or persons to whom the importer intends to transfer the listed chemical and the quantity to be transferred to each transferee.

(d) Any regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine must submit, on the import declaration, all information known to the importer on the chain of distribution of the chemical from the manufacturer to the importer. Ephedrine, pseudoephedrine, or phenylpropanolamine include each of the salts, optical isomers, and salts of optical isomers of the chemical.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995; 72 FR 17407, Apr. 9, 2007; 75 FR 10171, Mar. 5, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1313.14 Distribution of import declaration.

The required three copies of the listed chemical import declaration (DEA Form 486) will be distributed as follows:

(a) Copy 1 shall be retained on file by the regulated person as the official record of import. Import declaration forms involving a List I chemical must

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be retained for four years; declaration forms for List II chemical must be retained for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 6053 of the Chemical Diversion and Trafficking Act of 1988, as specified in § 1313.12.

(c) Copy 3 shall be presented to the U.S. Customs Service along with the customs entry. If the import is a regulated transaction for which the 15-day advance notice requirement has been waived, the regulated person shall declare this information to the U.S. Customs Service Official by checking the block on the DEA Form 486 designated for this purpose.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995; 77 FR 4237, Jan. 27, 2012]

§ 1313.15 Waiver of 15-day advance notice for regular importers.

(a) Each regulated person seeking designation as a “regular importer” shall provide, by certified mail return receipt requested, to the Administration such information as is required under § 1313.08 documenting their status as a regular importer.

(b) Each regulated person making application under paragraph (a) of this section shall be considered a “regular importer” for purposes of waiving the 15-day advance notice, 30 days after receipt of the application by the Administration, as indicated on the return receipt, unless the regulated person is otherwise notified in writing by the Administration.

(c) The Administrator, may, at any time, disqualify a regulated person's status as a regular importer on the grounds that the chemical being imported may be diverted to the clandestine manufacture of a controlled substance.

(d) Unless the Administration notifies the chemical importer to the contrary, the qualification of a regular importer of any one of these three chemicals, acetone, 2-Butanone (MEK), or toluene, qualifies that importer as a regular importer of all three of these chemicals.

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(e) All chemical importers shall be required to file a DEA Form 486 as required by Section 1313.12.

[60 FR 32464, June 22, 1995, as amended at 62 FR 13969, Mar. 24, 1997; 72 FR 17407, Apr. 9, 2007]

§ 1313.16 Transfers following importation.

(a) In the case of a notice under § 1313.12(a) submitted by a regulated person, if the transferee identified in the notice is not a regular customer, the importer may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the notice is submitted to the Administration.

(b) After a notice under § 1313.12(a) or (d) is submitted to the Administration, if circumstances change and the importer will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the importer must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to the Administration, except that the 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under § 1313.12(a) or (d).

(c) In the case of a transfer of a listed chemical that is subject to a 15-day restriction, the transferee involved shall, upon the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Administration otherwise notifies the importer involved in writing.

(d) With respect to a transfer of a listed chemical with which a notice or update referred to in § 1313.12(a) or (d) is concerned:

(1) The Administration—

(i) May, in accordance with the same procedures as apply under §§ 1313.51 through 1313.57, order the suspension of the transfer of the listed chemical by the importer involved, except for a transfer to a regular customer, on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred), subject to the Administration ordering the suspension before the expiration of the 15-day period with respect to the importation (in any case in which such a period applies); and

(ii) May, for purposes of this paragraph (d), disqualify a regular customer on that ground.

(2) From and after the time when the Administration provides written notice of the order under paragraph (d)(1)(i) of this section (including a statement of the legal and factual basis for the order) to the importer, the importer may not carry out the transfer.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an importer transfers a listed chemical.

[72 FR 17407, Apr. 9, 2007]

§ 1313.17 Return declaration or amendment to Form 486 for imports.

(a) Within 30 days after a transaction is completed, the importer must send to the Administration a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and any other information as the Administration may specify. A single return declaration may include the particulars of both the importation and distribution. If the importer has not distributed all chemicals imported by the end of the initial 30-day period, the importer must file supplemental return declarations no later than 30 days from the date of any further distribution, until the distribution or

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other disposition of all chemicals imported under the import notification or any update are accounted for.

(b) If an importation for which a Form 486 has been filed fails to take place, the importer must file an amended Form 486 notifying the Administration that the importation did not occur.

[72 FR 17408, Apr. 9, 2007]

EXPORTATION OF LISTED CHEMICALS

§ 1313.21 Requirement of authorization to export.

(a) No person shall export or cause to be exported from the United States any chemical listed in § 1310.02 of this chapter, which meets or exceeds the threshold quantities identified in § 1310.04(f) or is a listed chemical for which no threshold has been established as identified in § 1310.04(g) of this chapter, until such time as the Administrator has been notified. Notification must be made not later than 15 days before the transaction is to take place. In order to facilitate the export of listed chemicals and implement the purpose of the Act, regulated persons may wish to provide notification to the Administration as far in advance of the 15 days as possible.

(b) A completed DEA Form 486 must be received by the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the exportation. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration through electronic facsimile media not later than 15 days prior to the exportation.

(c) The 15-day advance notification requirement for listed chemical exports may be waived for:

(1) Any regulated person who has satisfied the requirements of § 1313.24 for reporting to the Administration an established business relationship, as defined in § 1300.02 of this chapter, with a foreign customer.

(2) A specific listed chemical to a specified country, as set forth in paragraph (f) of this section, for which the Administrator determines that ad-

vance notification is not necessary for effective chemical diversion control.

(d) For exports where advance notification is waived pursuant to paragraph (c)(1) of this section, the DEA Form 486 must be received by the Drug Enforcement Administration, Chemical Operations Section, on or before the date of exportation through use of the mailing address listed in Section 1313.12(b) or through use of electronic facsimile media.

(e) For exportations where advance notification is waived pursuant to paragraph (c)(2) of this section, no DEA Form 486 is required; however, the regulated person shall file quarterly reports with the Import/Export Unit, Drug Enforcement Administration, no later than the 15th day of the month following the end of each quarter. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The report shall contain the following information regarding each individual exportation:

- (1) The name of the listed chemical;
- (2) The quantity and date exported;
- (3) The name and full business address of the foreign customer;
- (4) The port of embarkation; and
- (5) The foreign port of entry.

(f) The 15 day advance notification requirement set forth in paragraph (a) of this section has been waived for exports of the following listed chemicals to the following countries:

Name of Chemical	Country
[Reserved]	

(g) No person shall export or cause to be exported any listed chemical, knowing or having reasonable cause to believe the export is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the Act or the laws of the country to which the chemical is exported. The Administration will publish a notice of foreign import restrictions for listed chemicals of

which DEA has knowledge as provided in § 1313.25.

[54 FR 31665, Aug. 1, 1989, as amended at 59 FR 51367, Oct. 11, 1994; 60 FR 32464, June 22, 1995; 62 FR 13969, Mar. 24, 1997; 66 FR 46520, Sept. 6, 2001; 67 FR 49569, July 31, 2002; 75 FR 10683, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1313.22 Contents of export declaration.

(a) Any List I or List II chemical listed in § 1310.02 of this chapter which meets or exceeds the quantitative threshold criteria established in § 1310.04(f) of this chapter may be exported if that chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) Any regulated person who desires to export a threshold or greater quantity of a listed chemical shall notify the Administration through procedures outlined in § 1313.21 and distribute three copies of DEA Form 486 as directed in § 1313.23.

(c) The DEA Form 486 must be executed in triplicate and must include all the following information:

(1) The name, address, telephone number, telex number, and, where available, the facsimile number of the chemical exporter; the name, address, telephone number, telex number, and, where available, the facsimile number of the export broker, if any;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in § 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The proposed export date, the U.S. Customs port of exportation, and the foreign port of entry; and

(4) The name, address, telephone, telex, and where available, the facsimile number of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

(d) Notwithstanding the time limitations included in paragraph (b) of this section, a regulated person may receive a waiver of the 15-day advance notifica-

tion requirement following the procedures outlined in § 1313.24.

(e) Declared exports of listed chemicals which are refused, rejected, or otherwise deemed undeliverable may be returned to the U.S. chemical exporter of record. A brief written notification (this does not require a DEA Form 486) outlining the circumstances must be sent to the Import/Export Unit, Drug Enforcement Administration, following the return within a reasonable time. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. This provision does not apply to shipments that have cleared foreign customs, been delivered, and accepted by the foreign consignee. Returns to third parties in the United States will be regarded as imports.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995; 67 FR 49569, July 31, 2002; 75 FR 10683, Mar. 9, 2010]

§ 1313.23 Distribution of export declaration.

The required three copies of the listed chemical export declaration (DEA Form 486) will be distributed as follows:

(a) Copy 1 shall be retained on file by the chemical exporters as the official record of export. Export declaration forms involving a List I chemical must be retained for four years; declaration forms for list II chemical must be retained for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 6053 of the Chemical Diversion and Trafficking Act of 1988, as specified in § 1313.21

(c) Copy 3 shall be presented to the U.S. Customs Service at the port of exit for each export of a listed chemical or chemicals on or before the day of exportation, and when possible, along with the Shippers Export Declaration.

[54 FR 31665, Aug. 1, 1989, as amended at 60 FR 32465, June 22, 1995; 61 FR 51004, Sept. 30, 1996]

§ 1313.24 Waiver of 15-day advance notice for chemical exporters.

(a) Each regulated person shall provide to the Administration the identity

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and information listed in the definition of established business relationship in §1300.02 of this chapter for an established business relationship with a foreign customer not later than August 31, 1989.

(b) Not later than October 31, 1989, each regular customer so identified in notifications made under §1313.24(a) shall be a regular customer for purposes of waiving the 15-day advance notice requirement, unless the regulated person is otherwise notified in writing by the Administration.

(c) Each foreign customer identified on an initial DEA Form 486 submitted after the effective date of the implementation of part 1313 shall, after the expiration of the 15-day period, qualify as a regular customer, unless the Administration otherwise notifies the regulated person in writing.

(d) Unless the Administration notifies the chemical exporter to the contrary, the qualification of a regular customer for any one of these three chemicals, acetone, 2-Butanone (MEK), or toluene, qualifies that customer as a regular customer for all three of these chemicals.

(e) The Administrator may notify any chemical exporter that a regular customer has been disqualified or that a new customer for whom a notification has been submitted is not to be accorded the status of a regular customer. In the event of a disqualification of an established regular customer, the chemical exporter will be notified in writing of the reasons for such action.

[54 FR 31665, Aug. 1, 1989, as amended at 56 FR 55077, Oct. 24, 1991; 62 FR 13969, Mar. 24, 1997; 75 FR 10684, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1313.25 Foreign import restrictions.

Any export from the United States in violation of the law of the country to which the chemical is exported is subject to the penalties of Title 21 United States Code 960(d).

§ 1313.26 Transfers following exportation.

(a) In the case of a notice under §1313.21(a) submitted by a regulated person, if the transferee identified in the notice, *i.e.*, the foreign importer, is

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not a regular customer, the regulated person may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the notice is submitted to the Administration.

(b) After a notice under §1313.21(a) is submitted to the Administration, if circumstances change and the exporter will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the exporter must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to the Administration, except that the 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under paragraph (a) of this section.

(c) In the case of a transfer of a listed chemical that is subject to a 15-day restriction, the transferee involved shall, upon the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Administration otherwise notifies the exporter involved in writing.

(d) With respect to a transfer of a listed chemical with which a notice or update referred to in §1313.21(a) is concerned:

(1) The Administration—

(i) May, in accordance with the same procedures as apply under §§1313.51 through 1313.57, order the suspension of the transfer of the listed chemical by the exporter involved, except for a transfer to a regular customer, on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that

may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred), subject to the Administration ordering the suspension before the expiration of the 15-day period with respect to the exportation (in any case in which such a period applies); and

(ii) May, for purposes of this paragraph (d), disqualify a regular customer on that ground.

(2) From and after the time when the Administration provides written notice of the order under paragraph (d)(1)(i) of this section (including a statement of the legal and factual basis for the order) to the exporter, the exporter may not carry out the transfer.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an exporter transfers a listed chemical.

[72 FR 17408, Apr. 9, 2007]

§ 1313.27 Return declaration or amendment to Form 486 for exports.

(a) Within 30 days after a transaction is completed, the exporter must send to the Administration a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and any other information as the Administration may specify.

(b) If an exportation for which a Form 486 has been filed fails to take place, the exporter must file an amended Form 486 notifying the Administration that the exportation did not occur.

[72 FR 17408, Apr. 9, 2007]

TRANSSHIPMENTS, IN-TRANSIT SHIPMENTS AND INTERNATIONAL TRANSACTIONS INVOLVING LISTED CHEMICALS

§ 1313.31 Advance notice of importation for transshipment or transfer.

(a) A quantity of a chemical listed in § 1310.02 of this chapter that meets or exceeds the threshold reporting requirements found in § 1310.04(f) of this chapter may be imported into the United States for transshipment, or

may be transferred or transshipped within the United States for immediate exportation, provided that advance notice is given to the Administration.

(b) Advance notification must be provided to the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the proposed date the listed chemical will transship or transfer through the United States. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address. The written notification (not a DEA Form 486) shall contain the following information:

(1) The date the notice was executed;

(2) The complete name and description of the listed chemical as it appears on the label or container.

(3) The name of the listed chemical as designated by § 1310.02 of this chapter.

(4) The number of containers and the size or weight of the container for each listed item;

(5) The net weight of each listed chemical given in kilograms or parts thereof;

(6) The gross weight of the shipment given in kilograms or parts thereof;

(7) The name, address, telephone number, telex number, business of the foreign exporter and, where available, the facsimile number;

(8) The foreign port of exportation;

(9) The approximate date of exportation;

(10) The complete identification of the exporting carrier;

(11) The name, address, business, telephone number, and, where available, the facsimile number of the importer, transferor, or transshipper;

(12) The U.S. port of entry;

(13) The approximate date of entry;

(14) The name, address, telephone number, telex number, business of the consignee and, where available, facsimile number of the consignee at the foreign port of entry;

(15) The shipping route from the U.S. port of exportation to the foreign port of entry at final destination;

(16) The approximate date of receipt by the consignee at the foreign port of entry; and

(17) The signature of the importer, transferor or transshipper, or his

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agent, accompanied by the agent's title.

(c) Unless notified to the contrary prior to the expected date of delivery, the importation for transshipment or transfer is considered approved.

(d) No waiver of the 15-day advance notice will be given for imports of listed chemicals in quantities meeting or exceeding threshold quantities for transshipment or transfer outside the United States.

[54 FR 31665, Aug. 1, 1989, as amended at 67 FR 49569, July 31, 2002; 75 FR 10684, Mar. 9, 2010; 77 FR 4237, Jan. 27, 2012]

§ 1313.32 Requirement of authorization for international transactions.

(a) A broker or trader shall notify the Administrator prior to an international transaction involving a listed chemical which meets or exceeds the threshold amount identified in Section 1310.04 of this chapter, in which the broker or trader participates. Notification must be made no later than 15 days before the transaction is to take place. In order to facilitate an international transaction involving listed chemicals and implement the purpose of the Act, regulated persons may wish to provide advance notification to the Administration as far in advance of the 15 days as possible.

(b)(1) A completed DEA Form 486 must be received by the Import/Export Unit, Drug Enforcement Administration, not later than 15 days prior to the international transaction. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(2) A copy of the DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Import/Export Unit, through electronic facsimile media not later than 15 days prior to the exportation.

(c) No person shall serve as a broker or trader for an international transaction involving a listed chemical knowing or having reasonable cause to believe that the transaction is in violation of the laws of the country to which the chemical is exported or the chemical will be used to manufacture a controlled substance in violation of the laws of the country to which the chemical is exported. The Administration

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will publish a notice of foreign import restrictions for listed chemicals of which DEA has knowledge as provided in Section 1313.25.

(d) After a notice under paragraph (a) of this section is submitted to the Administration, if circumstances change and the broker or trader will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the broker or trader must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be). The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under paragraph (a) of this section.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an exporter transfers a listed chemical.

[60 FR 32465, June 22, 1995; 61 FR 17566, Apr. 22, 1996; 67 FR 49569, July 31, 2002; 72 FR 17408, Apr. 9, 2007; 75 FR 10684, Mar. 9, 2010; 77 FR 4238, Jan. 27, 2012]

§ 1313.33 Contents of an international transaction declaration.

(a) An international transaction involving a chemical listed in § 1310.02 of this chapter which meets the threshold criteria established in § 1310.04 of this chapter may be arranged by a broker or trader if the chemical is needed for medical, commercial, scientific, or other legitimate uses.

(b) Any broker or trader who desires to arrange an international transaction involving a listed chemical which meets the criteria set forth in Section 1310.04 shall notify the Administration through the procedures outlined in Section 1313.32(b).

(c) The DEA Form 486 must be executed in triplicate and must include all the following information:

(1) The name, address, telephone number, and, where available, the facsimile number of the chemical exporter; the name, address, telephone number, and, where available, the facsimile number of the chemical importer;

(2) The name and description of each listed chemical as it appears on the label or container, the name of each listed chemical as it is designated in Section 1310.02 of this chapter, the size or weight of container, the number of containers, the net weight of each listed chemical given in kilograms or parts thereof, and the gross weight of the shipment given in kilograms or parts thereof;

(3) The proposed export date, the port of exportation, and the port of importation; and

(4) The name, address, telephone number, and, where available, the facsimile number of the consignee in the country where the chemical shipment is destined; the name(s) and address(es) of any intermediate consignee(s).

[60 FR 32465, June 22, 1995, as amended at 77 FR 4238, Jan. 27, 2012]

§ 1313.34 Distribution of the international transaction declaration.

The required three copies of the DEA Form 486 will be distributed as follows:

(a) Copies 1 and 3 shall be retained on file by the broker or trader as the official record of the international transaction. Declaration forms involving List I chemicals shall be retained for four years; declaration forms for two years.

(b) Copy 2 is the Drug Enforcement Administration copy used to fulfill the notification requirements of Section 1313.32.

[60 FR 32465, June 22, 1995; 60 FR 35264, July 6, 1995]

§ 1313.35 Return declaration or amendment to Form 486 for international transactions.

(a) Within 30 days after a transaction is completed, the broker or trader must send to the Administration a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of

transferees, and any other information as the Administration may specify.

(b) If a transaction for which a Form 486 has been filed fails to take place, the broker or trader must file an amended Form 486 notifying the Administration that the transaction did not occur.

[72 FR 17409, Apr. 9, 2007]

§ 1313.41 Suspension of shipments.

(a) The Administrator may suspend any importation or exportation of a chemical listed in § 1310.02 of this chapter based on evidence that the chemical proposed to be imported or exported may be diverted to the clandestine manufacture of a controlled substance. If the Administrator so suspends, he shall provide written notice of such suspension to the regulated person. Such notice shall contain a statement of the legal and factual basis for the order.

(b) Upon service of the order of suspension, the regulated person to whom the order applies under paragraph (a) of this section must, if he desires a hearing, file a written request for a hearing pursuant to §§ 1313.51–1313.57.

§ 1313.42 Prohibition of shipments from certain foreign sources.

(a) If the Administrator determines that a foreign manufacturer or distributor of ephedrine, pseudoephedrine, or phenylpropanolamine has refused to cooperate with a request by the Administrator for information known to the manufacturer or distributor on the distribution of the chemical, including sales, the Administrator may issue an order prohibiting the importation of the chemical in any case where the manufacturer or distributor is part of the chain of distribution.

(b) Not later than 60 days prior to issuing the order to prohibit importation, the Administrator shall publish in the FEDERAL REGISTER a notice of intent to issue the order. During the 60-day period, imports from the foreign manufacturer or distributor may not be restricted under this section.

[75 FR 10172, Mar. 5, 2010]

§ 1313.51

HEARINGS

§ 1313.51 Hearings generally.

In any case where a regulated person requests a hearing regarding the suspension of a shipment of a listed chemical, the procedures for such hearing shall be governed generally by the procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 6053 of the Chemical Diversion and Trafficking Act (Pub. L. 100–690), by 21 CFR 1313.52–1313.57, and by the procedures for administrative hearings under the Controlled Substances Act set forth in §§ 1316.41–1316.67 of this chapter.

§ 1313.52 Purpose of hearing.

If requested by a person entitled to a hearing, the Administrator shall cause a hearing to be held for the purpose of receiving factual evidence regarding the issues involved in the suspension of shipments within 45 days of the date of the request, unless the requesting party requests an extension of time.

§ 1313.53 Waiver of modification of rules.

The Administrator or the presiding officer (with respect to matters pending before him) may modify or waive any rule in this part by notice in advance of the hearing, if he determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

§ 1313.54 Request for hearing.

(a) Any person entitled to a hearing pursuant to § 1313.52 and desiring a hearing shall, within 30 days after receipt of the notice to suspend the shipment, file with the Administrator a written request for a hearing in the form prescribed in § 1316.47 of this chapter.

(b) If any person entitled to a hearing or to participate in a hearing pursuant to § 1313.41 fails to file a request for a hearing or a notice of appearance, or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

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(c) If all persons entitled to a hearing or to participate in a hearing waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to § 1313.57.

§ 1313.55 Burden of proof.

At any hearing regarding the suspension of shipments, the Agency shall have the burden of proving that the requirements of this part for such suspension are satisfied.

§ 1313.56 Time and place of hearing.

(a) If any regulated person requests a hearing on the suspension of shipments, a hearing will be scheduled no later than 45 days after the request is made, unless the regulated person requests an extension to this date.

(b) The hearing will commence at the place and time designated in the notice given pursuant to paragraph (a) of this section but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

§ 1313.57 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall issue his order regarding the suspension of shipment. The order shall include the findings of fact and conclusions of law upon which the order is based. The Administrator shall serve one copy of his order upon each party in the hearing.

PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

Subpart A—General

Sec.

- 1314.01 Scope.
- 1314.02 Applicability.
- 1314.03 Definitions.
- 1314.05 Requirements regarding packaging of nonliquid forms.
- 1314.10 Effect on state laws.
- 1314.15 Loss reporting.